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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,814	05/21/2004	Kenzo Yokozeki	252308US0CONT	8845

22850 7590 01/30/2007  
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/849,814

Applicant(s)

YOKOZEKI ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,8,9,11 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 9 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 9, 11, 13-18, 20-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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The examiner acknowledges The Amendment and Request for Reconsideration filed Oct. 25, 2006. Claim 4 has been previously cancelled; claims 2-3, 5, 7, 10 and 12, have been previously cancelled. Claims 1, 6, 8, 11, 13, 16, 18, 20 and 22 have been amended. Claims 1, 6, 8-9, 11, 13-22 are pending and under examination.

### **DETAILED ACTION**

#### **Priority**

Acknowledgment is made of applicants' certified translation of priority document Japanese application JP 2002-218958, filed 07/26/2002. The priority of the instant claims to JP 2002-218958, filed 07/26/2002, has not been granted.

#### **Objections**

Objections to claims 1 and 8 made in the Office action of July 25, 2006 (previous action) are withdrawn, because the claims have been amended.

#### **Rejections**

##### ***35 USC, section 112, second paragraph***

Rejection under this paragraph made in the previous action are withdrawn, because the claims have been amended.

##### ***35 USC, section 112, first paragraph***

***Lack of written description***

Claims 1, and claims 9 and 14 were rejected in the previous action and remain rejected for lack of description of the structure of enzyme used in the claimed method. The reasons are explained in the previous action.

***Scope of enablement***

***Rejections withdrawn***

Rejection of claims 6 and 8 made in the previous actions is withdrawn because after current amendmen the claims are enabled; they read on the enzyme being more than 98% identical to SEQ ID NO: 12 or amino acids 21-619 of SEQ ID NO: 12.

Rejection of claims 20 and 22 made in the previous action is withdrawn because he claims have been amended.

***Rejections not withdrawn***

Claims 1 and dependent claims 9 and 14 remain rejected for reasons explained in the previous actions.

***Response to Applicants' arguments***

In response to the rejection under 35 USC 112, for lack of written description a and scope of the enablement Applicants take position page 9 and 10 of REMARKS that the most important feature of the present invention is based on the finding that enzymatic reaction of the specific carboxy and amine component as defined in the present claim enables significant production of tri-or longer peptide in the manner

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presented in formula A at the top of page 10 REMARKS. Further Applicants admit that enzymatic methods of peptide production has been known in the art, however they require or costly raw materials or organic solvents, and has have low reaction yield, thus have not been appropriate for industrial use. Applicants go on arguing that the present invention is significantly more efficient and enables an industrial scale production of tripeptides with enzymatic reaction.

Applicants argument has bee fully considered but is found not persuasive because **Applicants do not address the reasons for rejection which is rejection for lack of written description and enablement** and not over a prior art.

Without providing a specific the structure of the enzyme which is to be used in the claimed method, the invention is not described and enabled.

### 3.3. 35 USC 102

Claim 1, 6 and 8 were rejected in the previous action under 35 U.S.C. 102(b) as being anticipating by Morihara et al. ( $\alpha$ -Chymotrypsin as the Catalyst of Peptide Synthesis, Biochem. J. 163, 531-542, 1977, enclosed in IDS). This rejection is now withdrawn, because the claims have been amended.

### Conclusion

Claims 1, 4, and 19 are rejected. Claims 6, 8, 9, 11, 13-18, and 20-22 are objected to as depending on rejected base claim.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

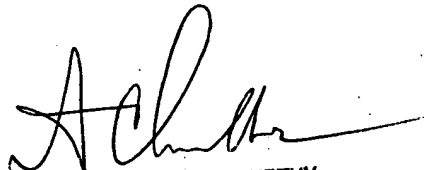
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.  
Art Unit 1652  
Patent Examiner



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SUPERVISOR/PATENT EXAMINER  
TECHNICAL STAFF